K063337

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
November 2, 2006

DEC 12 2006

Submitter's Information: 21 CFR 807.92(a)(1)

Viztek, Inc
6491 Powers Ave.
Jacksonville, FL 32217
Phone: 904.730.0446
Email: abasic@viztek.net

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Opal-RAD™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Classification Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)
Opal-RAD™ is substantially equivalent to:

510(k) Number	K032176
Regulation Number	892.2050
Device Name	RATTAN IMACS BY RATTAN INFORMATION CORPORATION
Applicant	RATTAN INFORMATION CORPORATION
Classification Product Code	LLZ
Decision Date	09/25/2003
Decision	substantially equivalent (SE)

Device Description: 21 CFR 807 92(a)(4)

Opal - RAD is a software suite of web based PACS applications that was developed specifically to handle the DICOM protocol, for both transmitting and viewing DICOM images and data elements. The applications were developed so that access to the PACS can occur from any Microsoft Windows computer with internet capabilities, and offer an interface that users find to be quite intuitive after some initial learning. The Opal-RAD applications deal with all manner of DICOM images and modalities, including MR, CT, CR, US, and many others. These images can be viewed, manipulated, annotated, transmitted to other facilities, printed, animated and stored using the Opal-RAD suite.

The device is designed to be deployed over conventional networking infrastructure available in most healthcare organizations, and utilizes commercially available computer platforms (Intel Pentium-based) and operating

systems (Microsoft Windows 2000, Windows NT, and Windows 98). The system does not produce any original medical images.

Indications for Use: 21 CFR 807 92(a)(5)

Opal-RAD™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used.
Typical users of this system are trained professionals, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does not contact the patient, nor does it control any life sustaining devices.
A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for Opal-RAD™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

Opal-RAD™ has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Viztek, Inc.
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

DEC 12 2006

Re: K063337
Trade/Device Name: Opal-RAD™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2006
Received: November 8, 2006

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K063337

Device Name:
Opal-RAD™

Indications for Use:

Opal-RAD™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used.

Typical users of this system are trained professionals, nurses, and technicians.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

David A. Clymer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063337